UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.,
Plaintiff,

v.

CIVIL ACTION NO. 04-12457-PBS

ARTHREX, INC. and
PEARSALLS LTD.

Defendants.

MEMORANDUM AND ORDER

July 31, 2007

Saris, U.S.D.J.

In this case about braided sutures, both parties cross-moved for summary judgment on two of Arthrex's defenses: (1) that an adhesive is added to the tips of FiberWire, which stiffens the suture, thus materially affecting the basic and novel characteristics of the invention; and (2) that FiberWire avoids infringement under the reverse doctrine of equivalents. After consideration, the Court ALLOWS the plaintiff's motion and DENIES the defendants' motion.

A. The Tipping Point¹

Defendants state that an adhesive is added to the ends of FiberWire to stiffen the suture, prevent fraying, and help

¹ The summary judgment motions primarily focused on the effect of the FiberWire coating. The briefing on these ancillary issues was cursory. Indeed, defendants' discussion is limited to a 4-line argument in a footnote on page 18 of the brief. As such, it has arguably waived the issue.

doctors attach instruments, such as anchors, needles, and hooks, to the suture. Arthrex argues that the addition of this material, which covers approximately 1 inch of both ends of the FiberWire device, supports a non-infringement defense, because these tips improve the suture's handleability by facilitating attachment to instruments in a manner that materially affects the basic and novel characteristics of the suture.

Plaintiff responds that the presence of these tips is irrelevant as a matter of law; it argues that "as long as 36 or 16 inches of FiberWire infringes," then the entire suture infringes. (Pl.'s Mem. Supp. Summ. J. 10.) In support of this argument, plaintiff points to A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703 (Fed. Cir. 1983) (citing Temco Elec. Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328 (1928)), which stated:

It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.

See also SunTiger, Inc. v. Scientific Research Funding Group, 189

F.3d 1327, 1336 (Fed. Cir. 1999) ("we have never required that a claim read on the entirety of an accused device in order to infringe. If a claim reads merely on a part of an accused device, that is enough for infringement."). In other words, plaintiff submits that Arthrex cannot avoid infringement simply

by adding some adhesive onto the ends of the suture.

Arthrex retorts that the cases upon which DePuy Mitek relies do not apply here since they all address patents containing the open term of transition, "comprising," whereas the '446 Patent contains the partially open transitional phrase, "consisting essentially of." The term "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003). The "consisting essentially of" language in a patent claim can at times blur the distinction between the separate steps in an infringement analysis (claim construction and comparison of the construed claim to the accused device or method). Id.

Undeterred, DePuy Mitek offers two additional cases, both of which involve patents with the restrictive closed terms of transition, "consisting of." This transition term "does not exclude additional components or steps that are <u>unrelated</u> to the invention." <u>See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.</u>, 460 F.3d 1349, 1360-61 (Fed. Cir. 2006) (emphasis added) (holding that additional element "unrelated' to the claimed invention did not preclude infringement even where "consisting of" transitional phrase is used). In determining whether an unrelated additional component is excluded from the scope of the claim, a court must "determine what is limited by the 'consisting of' phrase."

Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331-1332 (Fed. Cir. 2004) (reversing summary judgment of noninfringement because addition of a spatula was unrelated to the claimed invention of a for a kit "consisting of" certain chemicals). Again, plaintiff's cases are not entirely on point because they involve a different transitional phrase.

To resolve this debate, the Court must return to the claim construction. In an earlier Markman opinion, I determined that the basic and novel characteristics of the '446 Patent were: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. DePuy Mitek, Inc. v.

Arthrex, Inc., No. 04-12457-PBS, slip op. (D. Mass. Jan. 31, 2007).

Here, the parties have not asked the Court to address the issue of the tipping as a matter of claim construction although this issue seems to be in the gray area between claim construction and infringement. The patent itself is silent regarding tipping. Whether or not defendants' suture infringes plaintiff's patent hinges on whether these tips materially affect the basic and novel characteristics of the suture described in the '446 Patent, notably the characteristics of "handleability"

and "pliability" that were identified in the earlier Markman opinion.

Arthrex points to deposition testimony to suggest that the tips materially affect the basic and novel characteristics: Kevin Grieff stated: "Tipping is to make the suture rigid so you can pass it through instruments." (Def.'s Ex. 30, 53:25-54:2.) Shelby Cook Kornbluth testified: "The original intent of tipping the suture is so that you can -- that the end of the suture is stiff enough to insert into a needle to attach or for a surgeon to put through a free needle so that they can use a suture without a needle on it." (Def.'s Ex. 14, 120:1-6.) Ilya Koyfman reported: "The tipping is a relatively rigid polymeric substance which allows for insertion of a suture into the needle." (Def.'s Ex. 16, 106:5.) Plaintiff, meanwhile, concedes that FiberWire has adhesive tips that perform some function, but notes that they are small and commonly used throughout the field. Pointing to brochures from Arthrex, plaintiff argues that Arthrex's tips are so small as to be insignificant to the product. Plaintiff also notes that these tips are primarily used for attaching the suture to anchors and needles. As such, they cannot improve pliability or handleability as described in the specification, primarily knot tie-down.

The specification reveals that the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 11.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 11.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 11. 6-8. These "[b] raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 11.8-10 (emphasis added).

The invention did not relate to how the suture handled when it was being attached to another surgical object, like a needle or an anchor. Accordingly, this Court finds as a matter of law that the tips do not materially affect the basic and novel characteristics of the '446 Patent that I identified in my Markman opinion. Thus, summary judgment for plaintiff is appropriate.

B. Reverse Doctrine of Equivalents²

In 1950, the Supreme Court in Graver Tank & Mfg. Co. v.

² The defendants raise their reverse doctrine of equivalents argument in a footnote to their brief. As such, the briefing on this issue is quite spartan.

<u>Linde Air Products Co.</u>, first articulated the "reverse doctrine of equivalents" as a defense to patent infringement, stating that:

where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement

339 U.S. 605, 608-609 (1950). Courts interpreting <u>Graver</u> have left little guidance on the parameters of the reverse doctrine of equivalents. One recent case, Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002), undercuts this doctrine as an "anachronistic exception," noting "[n]ot once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents." Id. Explaining that "when Congress enacted 35 U.S.C. § 112, after the decision in Graver Tank, it imposed requirements for the written description, enablement, definiteness, and means-plus-function claims that are co-extensive with the broadest possible reach of the reverse doctrine of equivalents," the Federal Circuit suggested that this arcane defense was largely disfavored because it had been subsumed by more comprehensive legislation. Id. (citations omitted).

Despite this ominous language regarding the continuing

viability of the reverse doctrine of equivalents defense, Graver
has only one foot in the grave. The Federal Circuit has recently instructed that the reverse doctrine of equivalents "is equitably applied based upon underlying questions of fact." Amgen Inc. v.
Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1351 (Fed. Cir.)
2004). The accused infringer must prove that although the asserted claim literally infringes on the accused device, "it has been so changed that it is no longer the same invention." Id.
The court cautioned that "it is error to conduct infringement analyses [based on this doctrine] in a vacuum, without reference to the claims at issue." Id. (rebuffing the defendant's attempt to avoid infringement under the doctrine, even though "the method by which [defendant] controls [DNA] transcription is not identical" to the transcription methods taught by the patent and the DNA promoter was in a different location).

Arthrex, relying on its expert Dr. Mukherjee, points out:

The specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and pliability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the precise opposite. UHMWPE (the alleged first fiber-forming material) is added for strength and PET (the alleged second fiber-forming material) is added to improve knot tying -- a well-known handleability characteristic.

(Def.'s Mem. Supp. Summ. J. Ex. 31 at 18.) Because FiberWire ostensibly turns the patent on its head, Arthrex argues that its

suture is so far changed in principle from the patented article that it performs the same or a similar function in a substantially different way.

As a preliminary matter, the specification discusses the role of the first and second set of yarns in a preferred embodiment. '446 Patent col.4 ll.9-40. The claim itself does not require that the two sets of yarns have the properties described by Dr. Mukherjee. Moreover, Mr. Grafton, Arthrex's former vice-president and designer of FiberWire, who testified that PET, one of the materials from the second group of fiberforming threads, makes FiberWire stronger because, without it, a PE-only suture had knot slippage. (Pl.'s Mem. Supp. Summ J. Ex. 12 at 51:22-52:15; 53:20-54:5.) Grafton also testified that FiberWire's UHMWPE is lubricous. Id. at 52-53. Therefore, it improves compliance, lubricity, and fiber-to-fiber movement, and therefore contributes to handling and pliability properties. (Id. at Ex. 6 at \P ¶ 38, 40, 41, 45), just as the '446 Patent teaches. Thus, from this undisputed evidence, it appears as if the characteristics of the two threads in FiberWire, UHMWPE and PET, both contribute to the strength and handleability of the suture as provided in the claim construction. In this manner, DePuy Mitek arques that FiberWire achieves the same result (a braided suture that uses two dissimilar materials to reap the benefits of each material) in a sufficiently similar manner.

This Court finds that DePuy Mitek's argument is the better

one. First, while it is undisputed that UHMWPE is stronger than generic PE, the evidence in the record establishes that UHMWPE in FiberWire contributes, at least in some degree, to the pliability, lubricousness, and knot tie-down capacity of the suture. Similarly, as defendants' expert concedes, PET, which is dissimilar from UHMWPE, also contributes to the strength characteristics of FiberWire. In sum, FiberWire achieves the same result as the '446 Patent, and it does not do so in a substantially different way.

ORDER

Plaintiff's motion for summary judgment [Docket No. 105] on the reverse doctrine of equivalents and on defendants' tipping argument is ALLOWED. Defendants' motion for summary judgment [Docket No. 107] on these issues is DENIED.

<u>S/PATTI B. SARIS</u> United States District Judge